IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF MICHELLE BERRY TAKEN AUGUST 9, 2013

BSC Counter Designation	**Objection**	**Plaintiffs Counter Designation to BSC Counter Designation**
mb040913, (Pages 24:14 to 25:18) 9 Q. Okay. Would it be fair in general terms to 10 describe at least part of your responsibilities as a 11 conduit between your team and the regulatory authority 12 you're dealing with? 13 A. That's correct.	25:9-13 FRE 401, 402, 403 FDA	
mb040913, (Page 35:1 to 35:6) 35 1 Q. There are CFRs or regulations which govern what 2 you can and cannot say to doctors. Fair? 3 A. Yes. 4 Q. Tell you how to identify safety signals, for 5 instance, and report those in a timely manner. Fair? 6 A. Fair.	35:1-6 FRE 401, 402, 403 FDA	

mb040913, (Page 40:9 to 40:12) 40 9 Q. Okay. Do you believe Polyform mesh is safe for 10 insertion into a woman's vagina? 11 A. We have experience from physicians that these 12 products are indeed safe.	40:9-12 FRE 401, 402, 403, 801, 802	*Counter Designation to BSC Counter* *mb040913, (Page 76:3 to 76:21)* *76* *3 Q. The next document is marked as Exhibit* *4 Number 75.* *5 (Pause)* *6 Q. Are you ready to proceed?* *7 A. Yes.* *8 Q. Okay. So on April 29th, 2009, Boston* *9 Scientific responds to Health Canada and provides them* *10 additional information. Fair?* *11 A. Yup.* *12 Q. All right. And so this particular document,* *13 the e-mail cover page is dated May 14th, 2009, correct?* *14 A. Yes.* *15 Q. And again, it's to Dan Krause, your colleague* *16 in Canada, correct?* *17 A. Yes.* *18 Q. And if we go to the next page, the title of it* *19 is, "Refusal to Issue a Medical Device License."* *20 Do you see that?* *21 A. Yes.* *mb040913, (Pages 77:8 to 78:4)* *77* *8 Q. And what they say in the second sentence is,* *9 "We regret to inform you that your application has been* *10 refused under Section 38 (2) of the medical devices* *11 regulations for the following reasons."* *12 Do you see that?* *13 A. Yes.* *14 Q. And what they say is, "The postmarket clinical*

		15 experience with the device demonstrates a much higher *16 rate of reported adverse events compared to its licensed* *17 predicate, the Polyform mesh."* *18 Do you see that?* *19 A. Yes.* *20 Q. And then it goes on to say, "Boston Scientific* *21 has not provided objective evidence that this issue has* *22 been successfully addressed."* *23 Did I read that correctly?* *24 A. Yes.* *78* *1 Q. Finally they say, "The conclusion is that the* *2 risk/benefit profile of the device is unacceptable."* *3 Did I read that correctly?* *4 A. Yes.* *mb040913, (Pages 79:20 to 80:1)* *79* *20 Q. Okay. And then Boston Scientific makes a* *21 decision to appeal Health Canada's decision, correct?* *22 A. That's correct.* *23 Q. And you were involved in that decision -- that* *24 process, correct?* *80* *A. I was involved in the process.* *mb040913, (Page 80:3 to 80:12)* *80* *3 MR. LOVE: I'd like to mark Exhibit Number 76.* *4 (Exhibit Number 76* *5 marked for identification)* *6 Q. And this is a series of e-mails, Ms. Berry.*

		7 And we're going to start at the back because logically *8 that's the most -- it goes from -- chronologically from* *9 the back to the beginning, and we'll work our way* *10 through the front. And we'll do that on a series of* *11 e-mails that we'll be talking about here over the course* *12 of the next few months.* *mb040913, (Pages 81:13 to 82:1)* *81* *13 if you* *14 look in the middle, it's 2 of 4. You receive an e-mail* *15 from Donna Gardner, your boss, correct?* *16 A. Correct.* *17 Q. And what she's doing is she's forwarding you* *18 this e-mail chain, correct?* *19 A. Yes.* *20 Q. And she says, "FYI, see this string of e-mails* *21 which include the reasons Pinnacle was rejected. I'm* *22 not sure how they came to that conclusion based upon our* *23 response."* *24 Correct?* *82* *1 A. Correct.* *mb040913, (Pages 83:5 to 84:4)* *83* *5 It says, "Ken, I just wanted to inform you that* *6 the Pinnacle pelvic floor repair kit application has now* *7 been officially rejected by Health Canada."* *8 Do you see that?* *9 A. Yes.* *10 Q. "They feel the complaint and MDR rate (risk)*

		11 exceeds the benefit of the device." *12 Did I read that correctly?* *13 A. Yes.* *14 Q. Okay. So he goes down and says, "I am going to* *15 be initiating the appeals process, but at this point it* *16 looks unlikely that we will be receiving a license in* *17 Canada until the product matures in some other markets* *18 and complaint rates and MDR rates start to decrease in* *19 relation to sales volume."* *20 Did I read that correctly?* *21 A. Yes.* *22 Q. So at least from Dan's perspective, Health* *23 Canada had rejected this application until, one, the* *24 product matures in other markets, right?* *84* *1 A. That's what's stated, yes.* *2 Q. And two, the complaint rates and MDR rates* *3 start to decrease, correct?* *4 A. Correct.* *mb040913, (Page 85:4 to 85:7)* *85* *4 Q. Okay. Let's go to the next document, and it's* *5 marked Exhibit Number 77.* *6 (Exhibit Number 77* *7 marked for identification)* *mb040913, (Page 85:15 to 85:24)* *85* *15 Q. If we could, go to the second page of this* *16 particular e-mail chain. And this is an e-mail from you*

		17 at the very bottom. Do you see that? *18 A. Yes.* *19 Q. And it's dated May 22nd, 2009. Do you see* *20 that?* *21 A. Yes.* *22 Q. So that's about a week and a half after Health* *23 Canada rejected your application for Pinnacle, correct?* *24 A. Yes.* *mb040913, (Pages 86:20 to 87:20)* *86* *20 Q. Let's go to your e-mail. You say, "Hi, Joe.* *21 As a followup to a discussion you had with Donna earlier* *22 this week, we will be appealing Health Canada's decision* *23 on the Pinnacle PFR kit anterior/apical submission, due* *24 June 10th."* *87* *1 Do you see that?* *2 A. Yes.* *3 Q. You say, "We would like for you to provide us* *4 with two graphs and their supporting data tables."* *5 Did I read that correctly?* *6 A. Yes.* *7 Q. You say, "The first graph will summarize the* *8 2008 data previously submitted to Health Canada in* *9 February."* *10 Did I read that correctly?* *11 A. Yes.* *12 Q. "The complaint rate should be on the Y axis and* *13 time in months on the X axis."*

		14 Did I read that correctly? *15 A. Yes.* *16 Q. "The second graph should show this same data* *17 but be updated to include the number of complaints* *18 through May 2009."* *19 Did I read that correctly?* *20 A. Yes.* *mb040913, (Pages 88:22 to 92:13)* *88* *22 Q. All right. Fair enough. And then we have a* *23 series of e-mails discussing various issues related to* *24 this, but I'm interested in the next one, the bottom* *89* *1 e-mail on the first page. And this is from a gentleman* *2 whose name I can't pronounce.* *3 How do you pronounce his name?* *4 A. Well, he went by Ram.* *5 Q. Ram?* *6 A. Yeah.* *7 Q. We'll call him Ram.* *8 And this is Tuesday, May 26th, 2009. Do you* *9 see that?* *10 A. Yes.* *11 Q. So that's four days after your e-mail to Joe,* *12 saying this is the information we're collecting,* *13 correct?* *14 A. Yes.* *15 Q. And then again it's regarding the Health Canada* *16 appeal. Do you see that?* *17 A. Yes.* *18 Q. And Ram says, "Hi all. Piz" --

		What is that? Please? *A. Please.* *Q. Gotcha.* *"Plz find the attached Excel file. The Sheet 1 will have all the rough data and the Sheet 2 will have both graphs."* *90* *Do you see that?* *A. Yes.* *Q. And so what he's doing, I assume, is sending the data that you asked to be collected to you, Joe, and Donna, correct?* *A. Correct.* *Q. Donna, if we go one e-mail above, e-mails you a day later, correct?* *A. Yes.* *Q. And what she says is, "Michelle. Can the month and year be added to this? Should we touch base on this to see where we are?"* *Do you see that?* *A. Yes.* *Q. And so the data had now been accumulated and sent to at least you, Joe, and Donna, correct?* *A. Correct.* *Q. And this is data that you're going to include in your appeal, I assume.* *A. Well, to be reviewed and -- Yes.* *Q. Okay. And then you have an e-mail the same day Donna e-mailed you, and it's from you at the top. Do you see that?* *A. Yes.* *91* *Q. And it's to Donna. You see that?* *A. Yes.*

		Q. And then it's regarding the Health Canada appeal, correct? *A. Yes.* *Q. What it says is, "Sure. I will have the graphs updated with the month and year along the X axis."* *Do you see that?* *A. Yes.* *Q. Go ahead and if you could for the jury read the rest of that paragraph.* *A. "After looking at the graphs that Ram created, I don't think we want to provide Health Canada, HC, the newer complaint data. I did not see the downward trend we were hoping for. The complaint rate was up again for April and May, and I asked Ram why this is and he was going to look into it for me to see if it can be explained."* *Q. Okay. Thank you. So the complaint-rate data for April and May of 2009 that you'd accumulated for your appeal went up, correct?* *A. That's what my e-mail states.* *Q. All right. And obviously the e-mail states it wasn't the trend that you were hoping for, correct?* *92* *A. Correct.* *Q. You were hoping to see a downward trend so that you could submit that data in support of your application, correct?* *A. Right. We were looking for a downward trend.*

		6 Q. Okay. Now, Health Canada had indicated *7 that based upon the data that you had previously* *8 submitted that the risk/benefit profile was* *9 unacceptable, correct?* *10 A. That's what they stated.* *11 Q. And obviously if you're appealing this, they're* *12 interested in complaint-rate data. Fair?* *13 A. Sure.* *mb040913, (Page 96:11 to 96:18)* *96* *11 Q. You were trying to convince Health Canada to* *12 approve your product, right?* *13 A. That's the appeal process.* *14 Q. Right. And the data that you were looking at* *15 didn't show the trends you hoped for, correct?* *16 A. On this particular date, that's what the data* *17 was showing. I don't know what happened subsequent to* *18 these e-mails.* *mb040913, (Page 97:7 to 97:11)* *97* *7 MR. LOVE: I'd like to go to the next exhibit,* *8 if we could. It's going to be marked as Exhibit* *9 Number 78.* *10 (Exhibit Number 78* *11 marked for identification)* *mb040913, (Page 97:15 to 97:23)* *97* *15 Q. This is an e-mail from you, correct?*

		16 A. Yes. *17 Q. And it is dated May 28th, 2009, correct?* *18 A. Correct.* *19 Q. And that's one day after your recommendation --* *20 your e-mail recommendation of the 27th not to submit the* *21 new data to Health Canada, correct?* *22 MR. KEENAN: I object to the form.* *23 A. That's correct.* *mb040913, (Page 98:6 to 98:20)* *98* *6 Q. Okay. And what you say to Donna and Rob is,* *7 "Good morning, Donna and Rob. I wanted to forward you* *8 my rough draft of the comprehensive document for our* *9 discussion today at 10:00."* *10 Do you see that?* *11 A. Yes.* *12 Q. "Please see the attachment above. Also for Rob* *13 I have attached the complaint data charts that quality* *14 sent to me earlier this week."* *15 Did I read that correctly?* *16 A. Yes.* *17 Q. "Per our discussion, the data does not appear* *18 to support our anticipated result of a downward trend."* *19 Did I read that correctly?* *20 A. Yes.* *mb040913, (Pages 100:12 to 101:6)*

		100 *12 MR. LOVE: Let's go ahead and mark that as* *13 Exhibit Number 79.* *14 (Exhibit Number 79* *15 marked for identification)* *16 Q. Okay. And this is one of the attachments to* *17 your e-mail. And this is actually the complaint data* *18 charts that are referenced in your original request,* *19 right?* *20 A. Correct.* *21 Q. And if we look at this particular chart, the* *22 top one actually shows that the rate indeed did* *23 increase, as you had suggested in your previous e-mail,* *24 correct?* *101* *1 A. I think if you look at the latter couple of* *2 months, 15, 16, 17, there is definitely an upward* *3 movement, but overall it's pretty flat.* *4 Q. I mean, in your e-mail you're referencing that* *5 upward trend, correct?* *6 A. At the end, correct.* *mb040913, (Page 101:7 to 101:12)* *101* *7 Let's go on to the next* *8 exhibit, which is your draft of the comprehensive* *9 document to Health Canada. And this will be Exhibit* *10 Number 80.* *11 (Exhibit Number 80* *12 marked for identification)* *mb040913, (Pages 107:11 to 108:6)*

		107 11 Q. The phrase "complaint rate is trending 12 downward" is the opposite of "complaint rate is trending 13 upward," correct? 14 A. Correct. 15 Q. All right. And you have upward trends in April 16 and May, correct? 17 A. I assume that's what these months -- it's 15, 18 16, 17. The months aren't listed. 19 Q. Well, according to your e-mail on the 27th, you 20 said the complaint rates were trending up in April and 21 May, correct? 22 A. That's correct. 23 Q. All right. And you had previously submitted 24 information to Health Canada from March '08 to 108 1 March '09, correct? 2 A. Correct. 3 Q. So the only new data you could submit would be 4 from April and May, correct? 5 MR. KEENAN: Objection to form. 6 A. That makes sense, yes. mb040913, (Pages 120:22 to 121:5) 120 22 Q. My question is simple. Is the information from 23 April '09 and May '09 included in this appeal? 24 A. No, it's not. 121 1 Q. Thank you. Okay. We know what ultimately 2 happened with the appeals process, correct? 3 A. Yes. 4 Q. It was approved, was it not?

		5 A. We received a license.
mb040913, (Page 67:19 to 67:24) 67 19 Q. Now, as I appreciate it, that product was 20 cleared in the United States in November of 2007. 21 A. Yes, that sounds about right. 22 Q. All right. And clearance is a little bit 23 different than approval. Correct? 24 A. Correct.	67:19-23(24) FRE 401, 402, 403 FDA	
mb040913, (Page 172:10 to 172:23) 172 10 could be included if it was something that I guess FDA 11 or others felt they wanted to put that information out 12 there. 13 Q. What about you? What about your company? What 14 about you feeling like you wanted to put it out there? 15 MR. KEENAN: I object to the form. 16 A. We work on these directions for use. We 17 provide information. We work hand in hand with the 18 regulatory agencies to ensure that we're providing 19 appropriate information to physicians. 20 Through our dialogue back and forth with FDA 21 and all of the various submissions we've had, they've 22 provided input on what adverse events we list. And we 23 comply with that.	172:10-23 FRE 401, 402, 403 FDA	
mb040913, (Pages 181:22 to 182:3) 181 22 The patient brochure that we worked on with the 23 advice and guidance of FDA, I know they themselves are 24 trying to get that information out to patients. And in 182 1 our most recent version of that document there's a web 2 address provided which FDA specifically asked us to do,	181:22-182:3 FRE 401, 402, 403 FDA	mb040913, (Page 182:7 to 182:14) 182 7 Q. It's not the FDA's product, correct? 8 A. Correct. 9 Q. You make all the profits off this product, 10 correct? 11 MR. KEENAN: I object to the form. 12 A. I do not make the profits.

3 and it talks to the summary, FDA's summary of harms.		13 Q. Your company makes the profits off this 14 product, correct? mb040913, (Page 183:7 to 183:14) 183 7 So along with those profits come obligations, 8 right? 9 A. Yes. 10 Q. Your obligation is to inform physicians and 11 patients so they can use your product safely, correct? 12 A. Yes. 13 Q. And rates of occurrences are relevant to a 14 risk/benefit analysis, correct?
mb040913, (Pages 283:1 to 291:2) *** 2 Q. There's been a lot of questions asked of you 3 about what rules and what kind of materials you rely 4 upon to do your job as a regulatory affairs consultant. 5 Talk to me a little bit about what those -- if 6 there is a document that's specifically drafted for 7 surgical mesh. And I'll mark that as Exhibit Number 94. 8 (Exhibit Number 94 9 marked for identification) 10 A. So in regulatory there are numerous documents 11 available to anybody in this profession, whether it be 12 the Code of Federal Regulations. But subsequently FDA 13 does publish guidance documents. 14 And the one you've presented here is the 15 "Guidance for the Preparation of Premarket Notification 16 Applications for a Surgical Mesh." 17 Q. Okay. And so this would be one document that 18 you would review and use as guidance as part of	285:2-291:2 FRE 401, 402, 403 FDA	

preparation for the submission of a medical device that would be surgical mesh? MR. MORELAND: Form. A. That's correct. Q. And directing your attention to the next page, page 1 -- I'm sorry. The next page. 286 In particular, if the jury -- there's a paragraph here that states, "Summary of information regarding safety and effectiveness upon which a equivalence determination can be made or a statement that such information will be made available to interested persons upon request." Is that an important part of this document and what does that mean to you? MR. MORELAND: Form. A. Well, the application for doing a premarket notification, we provide information to the agency for review. And there is a process in place that if they have questions or would like additional information that they have an avenue to do so. Q. Directing your attention to page 4 of this document, there are additional specifications with regard to biocompatibility. Are these part of the requirements for any device that you submit pursuant to this guidance document? MR. MORELAND: Form. A. That's correct. We provide summary of biocompatibility test data. Q. Okay. And with respect to the next page, 287 page 5, labeling, the jury has heard quite a bit of discussion about labeling. What is labeling and what role does the FDA have to review the labeling that we propose with respect to a particular device that is -- that consists of pelvic mesh? MR. MORELAND: Form.		

MR. ORENT: Objection. A. The labeling that we provide here, we typically would include maybe a copy of the outer box, the product label, which describes the product, what it is, what's in it. And then there's also the directions or instructions for use that would be packaged within that product. And so they would review that information. And again, their role is to determine whether or not we were substantially equivalent to the predicate devices. Q. Okay. With respect to -- There's been questions asked of you of something called patient brochures. Is that something that also the FDA will review and comment on? MR. MORELAND: Form. A. They have reviewed and commented on our patient brochures. 288 Q. Specifically patient brochures for the pelvic organ prolapse devices? MR. MORELAND: Form. A. That's correct. Q. And they have also commented on the directions for use, the DFU that was the subject of questions earlier? MR. MORELAND: Form. A. That is correct. They have. Q. And give us an example of something that they have asked us to add and we've added. MR. MORELAND: Form. A. We've added a few warnings, precautions, as well as adverse events following their review and feedback of our submission documents. Q. There's another document that I want to direct your attention to quickly, and it's also a guidance		

document. And I will mark this as Exhibit Number 95.
(Exhibit Number 95 marked for identification)
Q. And I had would ask you to identify this for me. What is this document?
A. This is the guidance for industry and FDA staff. It's the format for traditional and abbreviated

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510(k)s.
Q. And what significance does this have in your job?
A. This outlines how to go about creating an actual submission for a 510(k) process. And so it outlines all of the elements, what they're looking for, and what is the basis for our submission.
Q. The date of this is the fall of 2005. So would this have been an additional document you'd have used as part of the preparation of the 510(k) submissions for the pelvic organ prolapse devices?
MR. MORELAND: Form.
A. It is.
Q. I want now to -- Are there additional documents and regulations that are important to you in your position in regulatory that -- and if so, give the jury a sense for those.
MR. MORELAND: Form.
A. Well, one of the items that we included in our submission, again, because we followed this abbreviated 510(k) format, the abbreviated approach allows you to cite a more specific product guidance document. In this case, we referenced the surgical mesh guidance.
But it also allows to reference standards. And

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there are numerous standards. There are ISO standards,

2 ASTM, product test standards that exist for these types 3 of devices that cover both biocompatibility testing, 4 performance testing of the mesh, packaging -- testing of 5 the package, sterilization. 6 So we cited all of those standards that we 7 followed in providing this information to the agency. 8 Q. Okay. And just so we can give the jury a 9 sense -- big picture for the various devices that you 10 did submit to the FDA and that were cleared by the FDA, 11 if you could, just recite those. And if you could, give 12 some general approximate date for when those would have 13 been cleared by the FDA. 14 MR. MORELAND: Form. 15 A. So in the -- For the pelvic floor repair 16 products, the first one we talked about earlier is the 17 Pinnacle pelvic floor repair kits. And that submission 18 went in -- I'm trying to remember the exact date it went 19 in. It was cleared in, I want to say, November 2007. 20 And that's the K0810 -- now I'm going to -- K071957. 21 Q. And then go on to the next one. 22 A. And then the next one would have been our 23 Uphold vaginal support system, K081048. That one was 24 submitted it looked like it was in the spring, April 291 1 of 2008 or so, and was subsequently cleared in August 2 of 2008.		
mb040913, (Page 291:22 to 291:24) 291 22 Q. Okay. At any time was the clearance that was 23 granted to those devices ever rescinded or revoked by 24 the FDA?	291:22-24 FRE 401, 402, 403 FDA	

mb040913, (Page 292:2 to 292:2) 292 2 A. No, they were not	292:2 FRE 401, 402, 403 Foundation, FDA	
mb040913, (Pages 292:20 to 296:18) 292 20 Q. I want to briefly mark the 510(k) file for the 21 Pinnacle and the Uphold. Counsel earlier marked Exhibit 22 Number 93. Do you recall this? 23 A. Yes. 24 Q. And this represents just a part of the actual 293 1 510(k) submission. Correct? 2 A. Correct. 3 Q. Give the jury some sense for how the 510 4 submission, 510(k) submission, typically proceeds. 5 You make a submission. You hear back from the 6 FDA. And just give us a sense for how it typically will 7 proceed from there. 8 MR. MORELAND: Form. 9 A. So I mean, I can speak from experience in these 10 particular submissions. 11 After each one was submitted, FDA had some 12 questions. They would provide us a letter outlining the 13 questions that they had regarding our application, and 14 then a dialogue back and forth with the agency would 15 begin. Our correspondence with them was part in written 16 form as well -- via a formal submissions or in e-mails. 17 We also had numerous phone calls, conversations 18 with them, and those were documented in our file. 19 Q. Okay. I'm going to hand you Exhibit Number 96. 20 (Exhibit Number 96 21 marked for identification) 22 Q. And it is a -- it's a rather bulky document.	292:20-296:18 FRE 401, 402, 403 FDA	

23 Without getting too burdened into details, give the jury 24 some sense what this represents. 294 1 You reviewed this prior to the deposition? 2 A. Correct. 3 Q. Just take a minute to confirm that it is what 4 I'm representing it to be. 5 A. Right. So this is the K071957 submission, 6 which is the very first pelvic floor repair kit 7 submission, dated July 12th, 2007. 8 Q. Okay. And does this document reflect on Bates 9 Number 140000199 a letter from the FDA, dated 10 November 8th, 2007, in which they have cleared this 11 device? 12 A. That is correct. This is the clearance letter. 13 Q. And what does this represent? 14 A. That they've reviewed all the information that 15 was provided to them and that the device is safe and 16 effective. 17 Q. Okay. And for the jury's benefit, if it's 18 cleared on this date, it may not -- might not actually 19 be marketed for some time after that? 20 A. That is correct. 21 Q. Just a general sense. Are we talking about 22 several months? Are we talking about years? How long 23 typically does it take from the clearance to actually 24 beginning the process of selling this device? 295 1 A. Each product is -- will vary depending upon the 2 readiness of the product. In this case, FDA had 3 provided some feedback to us in the directions for use. 4 To make modifications or changes to those instructions 5 for use takes some time. It has to go through 6 translations, prints, review, and then packaging with 7 the device. So it takes a little bit of time to do 8 that.		

9 Q. But this exhibit would reflect the totality or 10 most of the give and take and exchanges from the FDA and 11 the revisions and whatnot? 12 MR. MORELAND: Form. 13 A. Correct. 14 Q. Okay. I also want to mark for you now the next 15 exhibit, which is Exhibit Number 97, which I'll 16 represent to you is the Uphold 510(k). 17 (Exhibit Number 97 18 marked for identification) 19 Q. And I'll ask you to take a brief moment to 20 review and confirm that this is, in fact, what it is. 21 (Pause) 22 A. Okay. So this is submission K081048, stamped 23 with an April 11th, 2008, date for when it was 24 submitted. 296 1 Q. Okay. And just like you described with the 2 Pinnacle, this would represent the -- among other 3 things, the submission to the FDA that would be in 4 conformity with the guidance document that we previously 5 marked as an exhibit? 6 MR. MORELAND: Form. 7 A. That's correct. We followed the guidance 8 documents and the information that's available to 9 provide a document that FDA can follow and easily read. 10 Q. Okay. And directing your attention to the 11 Bates number that ends in the numbers 405, this is an 12 August 22nd, 2008, letter. 13 And what does this represent? 14 A. This is the clearance letter stating that the 15 device is substantially equivalent. 16 Q. And this would be, then, the clearance from the 17 FDA to begin marketing the device? 18 A. That's correct.		
mb040913, (Pages 300:24 to 301:11) 300 24 Q. The directions for use that counsel marked as 301 1 Exhibit Number 83 and took you through contains specific	300:24-301:11 Foundation	

2 language, did it not, that doctors be trained? 3 MR. MORELAND: Form. 4 MR. LOVE: I object to form. 5 A. Correct. 6 Q. Let's go to Exhibit Number 83. And Exhibit 7 Number 83 in the precautions -- 8 MR. KEENAN: You can zoom in on that a little. 9 Q. So Michelle, this was in the Uphold directions 10 for use? 11 A. Yes.		
mb040913, (Pages 312:6 to 313:18) 312 6 Q. But this is a document that attempts to capture 7 all of the complaint data the company had at the time, 8 right? 9 MR. MORELAND: Form. 10 A. That is correct. 11 Q. In other words, if I wanted to know what the 12 totality of the company's complaint data was on 13 Pinnacle, Uphold, and Pinnacle LITE, this is the place 14 I'd go to, right? 15 A. Correct. 16 Q. And if I had someone like Allison, she could 17 take the jury through this document and explain the 18 biostatistical summary that goes into this? 19 MR. MORELAND: Form. 20 A. Yes. 21 Q. Someone other than you? 22 A. Yes. 23 Q. But this document does attempt to capture all 24 the peer-reviewed literature that's out there, whether 313 1 involving our products or similar products, correct? 2 MR. MORELAND: Form. 3 A. That's correct. 4 Q. So when Mr. Love was identifying for the jury's 5 benefit -- when he was identifying for you particular	312:16-20 Foundation	

6 rates of occurrence, this is reflective of harms in the 7 literature for synthetic pelvic mesh pelvic floor kits 8 no matter the manufacturer, right? 9 MR. MORELAND: Form. 10 A. That's correct. 11 Q. If we were to go to the footnotes, it would 12 identify the particular study that's reflecting those 13 statistics? 14 A. That is correct. 15 Q. And I think, as Mr. Love noted and I think you 16 acknowledge, some of these statistics vary widely. 17 MR. MORELAND: Form. 18 A. They do.		

1. **Objections to Counter Exhibits.**

    a. Plaintiffs object to Berry 94 under FRE 401, 402, and 403 as it contains FDA references
    b. Plaintiffs object to Berry 95 under FRE 401, 402, and 403 as it contains FDA references.
    c. Plaintiffs object to Berry 96 under FRE 401, 402, and 403 as it contains FDA references.
    d. Plaintiffs object to Berry 97 under FRE 401, 402, and 403 as it contains FDA references.

2. **Counter Exhibits to Counter Exhibits**

    a. Berry 75
    b. Berry 76
    c. Berry 77
    d. Berry 78
    e. Berry 79
    f. Berry 80
    g. Berry 81
    h. Berry 82

DATED: July 20, 2015

Respectfully Submitted,

TRACEY & FOX LAW FIRM

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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